IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA

OrthoAccel Technologies Inc.,)
Plaintiff,) Civil Action No
v.)
Devicix, LLC,) COMPLAINT AND JURY DEMAND
Defendant.)
)

Plaintiff, OrthoAccel Technologies Inc. ("OrthoAccel"), by and through its counsel, North Rose Fulbright US LLP, files this Original Complaint against Devicix, LLC ("Devicix") and states as follows:

NATURE OF THIS ACTION

1. This is an action to recover damages that OrthoAccel incurred to remedy defects in its AcceleDent Aura device caused by Devicix's improper design and development of the device. Contrary to Devicix's representations, it lacked the requisite skill and expertise to properly design and develop the device and, as a result, the device contained numerous latent defects. OrthoAccel launched its AcceleDent Aura device to the market relying on Devicix's representations and assurances, yet end users of the device encountered numerous problems caused by Devicix's failure to properly design the device. OrthoAccel suffered millions of dollars in damages in addressing customers' complaints and fixing Devicix's faulty design, replacing faulty devices, among other things, in addition to the substantial sums it paid Devicix and the sales and goodwill it lost as a result.

PARTIES

- 2. OrthoAccel Technologies Inc. is a company incorporated under the laws of the state of Delaware, with its principal place of business in Bellaire, Texas.
- 3. Defendant Devicix, LLC is a limited liability company formed under the laws of the State of Minnesota with its principal place of business in Eden Prairie, Minnesota. Upon information and belief, all of the members of Devicix, LLC are citizens of Minnesota.

JURISDICTION AND VENUE

- 4. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332 because complete diversity of citizenship exists between the parties and the amount in controversy exceeds \$75,000.00, exclusive of interests and costs.
- 5. Venue is proper under 28 U.S.C. § 1391 because a substantial part of the events giving rise to the claim occurred in the District of Minnesota. Devicix is subject to personal jurisdiction in the district and has, at all relevant times, operated its business in this judicial district.

FACTUAL ALLEGATIONS

- 6. OrthoAccel is a medical device company currently engaged in the development, manufacturing, and marketing of products to enhance dental care and orthodontic treatment.
- 7. OrthoAccel previously developed and sells AcceleDent, the first FDA-cleared clinical approach to safely accelerate orthodontic tooth movement by applying gentle micropulses as a complement to existing orthodontic treatment.
- 8. Following the release of the AcceleDent product, OrthoAccel planned to develop and release a new device, the AcceleDent Aura.

- 9. To this end, OrthoAccel prepared a Request for Quote (RFQ) seeking information from several design firms, including Devicix, about their capabilities of designing and developing the AcceleDent Aura.
- 10. Devicix responded to the RFQ, specifically representing its qualifications and capabilities in design and design controls as well as medical device development.
- 11. Devicix further touted its expertise in industrial design and engineering capabilities, both in oral representations to OrthoAccel executives and in print.
- 12. OrthoAccel hired Devicix to provide design and development services on the AcceleDent Aura, pursuant to Proposal #021-005 (the "Contract") on July 15, 2011.
- 13. The work on the AcceleDent Aura project was performed pursuant to the Contract as well as various purchase work orders issued under the Contract during the course of the project.
- 14. In the Contract, Devicix promised to perform its design services "in a competent, professional, workman-like manner in accordance with industry standards."
- 15. The Contract included a provision in which Devicix warranted that "Deliverables provided by Devicix will conform to the applicable specifications stated in the Project Description."
- 16. In the Contract, Devicix agreed to design specifications for the AcceleDent Aura device, including requirements that:
 - a. The device "be designed for a 5 year product life";
 - b. The device have a "minimum shelf life of two (2) years";

- c. The device be "[c]apable of delivering five (5) complete treatment sessions per full charge";
- d. The batteries be "capable of recharging 300 times"; and
- e. Devicix complete a "five (5) year accelerated life test".
- 17. Devicix knew that OrthoAccel did not have the equipment nor technical expertise to test the AcceleDent Aura product it hired Devicix to design, and that OrthoAccel was relying upon Devicix to properly design and test the product before OrthoAccel launched it to the market.
- 18. Devicix's AcceleDent Aura design process was plagued by setbacks, including a repeated inability to satisfy deadlines, budgets, and specifications. OrthoAccel expressed to Devicix its concerns about Devicix's ability to complete the project, and in response, Devicix's CEO, Peter DeLange, traveled to OrthoAccel's offices in Bellaire, Texas, in September 2012.
- 19. In that September 2012, meeting, Mr. DeLange admitted Devicix's failings and acknowledged OrthoAccel's concerns about Devicix's ability to properly complete the AcceleDent Aura project. Mr. DeLange told OrthoAccel's CEO, Mike Lowe, that he understood how important the AcceleDent Aura project was, that Devicix had the expertise to properly complete the project, and that Devicix would fix the problems with the device and "get it right." In reliance upon those assurances, OrthoAccel allowed Devicix to continue working on the AcceleDent Aura project.
- 20. In reliance upon Devicix's work, its representations regarding that work, and its testing of its design, OrthoAccel released the AcceleDent Aura product to the market on or about May 6, 2013.

- 21. OrthoAccel began receiving customer complaints related to the design and resulting operation of the AcceleDent product upon being launched to the market.
- 22. Investigating these customer complaints, OrthoAccel continued to discover problems in Devicix's design and development of the product.
- 23. OrthoAccel notified Devicix of the customer complaints it had received and the problems it had identified in the design and development of the product, and demanded that Devicix remedy them.
- 24. In response, Devicix repeatedly demanded payment to remedy the defects in its design. Given the immediate need for fixes, OrthoAccel assented.
- 25. However, in attempting to remedy the defects in its design, Devicix only created new problems and defects.
- 26. Devicix failed to design the AcceleDent Aura in a competent, professional, and workmanlike manner and this failure caused numerous defects and problems with Devicix's design and development of the AcceleDent Aura product including:
 - a. The unit drained the battery in fewer than 50 days and would no longer accept a charge, causing the unit to become inoperable in under 2 months far earlier than the specified 2-year shelf life.
 - b. The unit was designed outside of the component manufacturer's specifications for the battery charger integrated circuit, optical sensor, and power supply integrated circuit.

- c. The unit's battery charge indicator did not accurately depict the battery's charge.

 When Devicix attempted to remedy this problem after launch, its "solution"

 exacerbated the battery drainage problem.
- d. The unit was specified to have snap-fit housing, but Devicix's design required glue to hold the unit together.
- e. The motor was not properly retained in the housing, causing a no-run condition after the motor shifted during normal product use.
- f. Ambient reflectivity was not taken into account in the design of the optical sensor, necessitating hand painting the encoder wheel.
- g. Devicix's design of the product caused the unit to fail when its button was depressed more than one time. Devicix's "solution" after launch enabled a timer that caused the device to lock up after 120-130 days of use.
- h. The software architecture was designed such that the unit does not enter the lowest power sleep state when turned off, contributing to the battery issue described above.
- i. The unit did not perform to relative humidity specification.
- 27. When it became clear that Devicix's design of the AcceleDent Aura product was defective and substandard, that it failed to meet the industry warranty of performing design work in a competent, professional and workmanlike manner, and that Devicix also could not remedy its poor work, OrthoAccel communicated with Devicix's CEO, Peter DeLange.
- 28. Mr. DeLange denied all responsibility for the design defects and instead blamed OrthoAccel. Specifically, Mr. DeLange claimed that despite Devicix's purported design and

development expertise, OrthoAccel could not rely on this expertise but rather OrthoAccel "assume[d] full responsibility for [Devicix's] designs" by approving them.

- 29. Unable to rely on Devicix to even remedy its prior defective work on the AcceleDent Aura product, OrthoAccel was forced to take remedial action itself. Among other things, OrthoAccel hired another engineering and design services firm to correct the deficiencies in Devicix's designs.
- 30. As a result of the defects in the device described above, OrthoAccel suffered economic and non-economic damages in an amount in excess of \$75,000, including the following:
 - a. The sums paid to Devicix to design the AcceleDent Aura product and to attempt to remedy the flaws in that design.
 - b. The sums OrthoAccel paid to another engineering and design firm to correct the deficiencies in Devicix's designs, when Devicix was unable to correct them itself.
 - c. In addition to costs paid to outside vendors, OrthoAccel sustained significant internal costs. OrthoAccel's operations and sales personnel spent substantial amounts of time working to address and correct problems related to Devicix's design flaws, thus resulting in extensive expenses for OrthoAccel.
 - d. In addition to the costs for correcting design flaws, which would correct future production runs of the AcceleDent Aura device, OrthoAccel also incurred costs to correct problems with the devices that had already been distributed to orthodontists.

OrthoAccel had to hire a firm that provided a specialize team to test and repair AcceleDent Aura units in hundreds of orthodontists' offices across the county.

- e. OrthoAccel has incurred, and continues to incur, costs to correct problems with devices held by end-users. These costs include the expenses associated with providing functional replacement devices to consumers as well as the shipping expense both to and from consumers.
- f. OrthoAccel also incurred significant costs that were required to perform corrective measures on the devices that were already manufactured but had not yet been sold to either a reseller or end user.
- g. The problems with the AcceleDent Aura device severely damaged OrthoAccel's reputation among both dispensing orthodontists and end-user patients in the market.
- h. Devicix's defective design and the resultant damage to OrthoAccel's reputation has caused lost past and future sales of the AcceleDent Aura device and lost business from OrthoAccel's current and potential customers and business development sources, and lost goodwill.

FIRST CLAIM FOR RELIEF Fraud in the Inducement

- 31. OrthoAccel incorporates herein all paragraphs previously set forth.
- 32. In its response to OrthoAccel's RFQ, Devicix represented to OrthoAccel that it had the requisite skill and expertise to design and develop the AcceleDent Aura product for OrthoAccel. These representations were based upon and touted the fact that Devicix's engineering and program management teams were "highly experienced in medical device

development," that Devicix had "extensive experience" in "developing" and "upgrading a variety of electromechanical devices . . . like AcceleDent," and that Devicix had expanded capabilities to meet customer needs including "industrial design . . . [and] manufacturing capabilities."

- 33. Devicix's representations regarding its abilities to design and develop the AcceleDent Aura were false.
- 34. Devicix's representations had to do with past or present facts, were material, and were susceptible of knowledge.
- 35. At the time it made its representation, Devicix knew that the representation was false or made the representation recklessly and without regard to its truth or falsity. Upon information and belief, Devicix overstated its design and development capabilities, representing that it had the requisite skills to develop the AcceleDent Aura device. Despite given numerous opportunities, Devicix has shown it did not have the requisite skills to properly design the AcceleDent Aura.
 - 36. Devicix intended to induce OrthoAccel to act based upon its representation.
- 37. In the proposed and executed Contract, and repeatedly in meetings and orally, Devicix promised to design the AcceleDent Aura product to specifications and perform its services in a competent, professional, workman-like manner in accordance with current industry standards.
- 38. Upon information and belief, when Devicix made those promises, it lacked the present intent to fulfill its promises. Devicix's CEO, Peter DeLange, has suggested this in his correspondence to OrthoAccel dated August 14, 2014 and August 28, 2014, in which he stated that OrthoAccel "assume[d] full responsibility for the designs [it] approved" and had "ultimate

responsibility for the overall outcome of the development," even though Devicix knew that OrthoAccel was relying on Devicix's purported expertise and promised performance.

- 39. Devicix's false promises had to do with past or present facts, were material, and were susceptible of knowledge.
 - 40. Devicix intended to induce OrthoAccel to act based upon its false promises.
- 41. OrthoAccel relied upon Devicix's representations and false promises and was deceived by them. Specifically, OrthoAccel relied upon the representations made by Devicix when it entered into the Contract and made periodic payments to Devicix pursuant to the Contract.
 - 42. OrthoAccel acted with ordinary prudence in relying on Devicix's representations.
- 43. Devicix's false representations and promises were the proximate cause of OrthoAccel's damages, which are in an amount in excess of \$75,000.
- 44. In the alternative to its contract claims below, OrthoAccel is entitled to the remedy of rescinding the Contract and suing for full tort damages because Devicix fraudulently induced OrthoAccel to enter into the Contract.

SECOND CLAIM FOR RELIEF Negligent Misrepresentation and Omission

- 45. OrthoAccel incorporates herein all paragraphs previously set forth.
- 46. Devicix, in the course of its business, supplied false information to OrthoAccel. Devicix supplied false information in the form of representations regarding its product design capabilities, representations that Devicix would provide services in a competent, professional, and workman like manner, representations about the status of Devicix's performance of the Contract, and representations that Devicix had the requisite skill and expertise to design and

develop the AcceleDent Aura product for OrthoAccel. These representations were based upon and touted the fact that Devicix's engineering and program management teams were "highly experienced in medical device development," that Devicix had "extensive experience" in "developing" and "upgrading a variety of electromechanical devices . . . like AcceleDent," and that Devicix had expanded capabilities to meet customer needs including "industrial design . . . [and] manufacturing capabilities."

- OrthoAccel numerous material facts that caused OrthoAccel to be unaware of the defects at the time of its release, including: Devicix failed to notify OrthoAccel that the battery installation in the AcceleDent Aura failed to meet industry standards; Devicix failed to advise OrthoAccel that it had designed the AcceleDent Aura device outside of the component manufacturer's specifications for the battery charger integrated circuit, optical sensor, and power supply integrated circuit; failed to inform OrthAccel that the product would not have a two year shelf life; failed to state that Devicix deviated from industry standard in the design and development of the product; failed to advise OrthoAccel that the battery in the device could not be recharged after going dead; failed to tell OrthoAccel that Devicix's design prevented the device from entering the lowest power mode when turned off; and failed to inform OrthoAccel that the device would not perform to the relative humidity specification.
- 48. Devicix provided this information for OrthoAccel's guidance in its business transactions. Additionally, Devicix omitted material information OrthoAccel needed to guide its business transactions. Specifically, these representations and omissions were made in order to

guide OrthoAccel in its selection of a design and development vendor to partner with in developing the AcceleDent Aura device.

- 49. Devicix failed to exercise reasonable care in obtaining or communicating this information because Devicix knew or should have known that it lacked the capability to design and develop the AcceleDent Aura device. Devicix knew or should have known that the product specifications that OrthoAccel provided to Devicix during the RFQ process required greater technical expertise and skill than Devicix could provide.
- 50. OrthoAccel justifiably relied on the information Devicix provided by assenting to the Contract based on these representations and making periodic payments to Devicix pursuant to the Contract.
- 51. OrthoAccel suffered damages in an amount in excess of \$75,000 based Devicix's misrepresentations.
- 52. In the alternative to its contract claims below, OrthoAccel is entitled to the remedy of rescinding the Contract and suing for full tort damages because Devicix's negligent misrepresentations induced OrthoAccel to enter into the Contract.

THIRD CLAIM FOR RELIEF Negligent Performance of Professional Services/Professional Liability

- 53. OrthoAccel incorporates herein all paragraphs previously set forth.
- 54. Devicix, as a professional design firm, owed OrthoAccel a duty to perform its services in a professional and workmanlike manner and in a way that conforms to the practices and procedures of a reasonably prudent professional design consultant.

- 55. Devicix breached its duty by failing to perform its services in a professional and workmanlike manner and in a way that conforms to the practices and procedures of a reasonably prudent professional design consultant, including:
 - a. Failing to design the AcceleDent Aura product in a commercially viable manner.
 - b. Providing a product design that contained latent defects that caused the product to cease functioning before or shortly after delivery to end-users.
 - c. Designing the product outside of the manufacturer's specifications for the battery charger circuit, optical sensor, and power supply output.
- 56. OrthoAccel suffered damages in an amount in excess of \$75,000 that were caused by Devicix's negligence.

FOURTH CLAIM FOR RELIEF Breach of Contract

- 57. OrthoAccel incorporates herein all paragraphs previously set forth.
- 58. OrthoAccel contracted with Devicix for design services on July 15, 2011.
- 59. The Contract specified that Devicix would:
 - a. Design the device to have a five year product life;
 - b. Design the device to have a minimum shelf life of two years;
 - c. Design the device to be capable of delivering five complete treatment sessions per full charge;
 - d. Design the device with batteries capable of recharging 300 times;
 - e. Complete a five year accelerated life test on the device; and
 - f. Perform its services in a competent, professional, workman-like manner in accordance with current industry standards.

- 60. Devicix failed to perform these contractual obligations.
- 61. Devicix's failure to perform its duties under the Contract caused economic and non-economic damages to OrthoAccel in an amount in excess of \$75,000, as detailed above.
- 62. The Contract purports to limit Devicix's liability and limit OrthoAccel's remedies for breach of warranties, however the circumstances of this dispute cause Devicix's attempted damage limitations to fail of their essential purpose and are unconscionable.
- 63. Devicix's breach caused damages to OrthoAccel in an amount in excess of \$75,000.

FIFTH CLAIM FOR RELIEF Breach of Warranty

- 64. OrthoAccel incorporates herein all paragraphs previously set forth.
- 65. OrthoAccel contracted with Devicix for design services on July 15, 2011.
- 66. The Contract warranted that the "[d]eliverables provided by Devicix will conform to the applicable specifications stated in the Project Description."
- 67. Devicix further warranted that its services would "be performed in a competent, professional, workman-like manner in accordance with current industry standards."
- 68. Devicix breached its warranties by delivering a device that failed to meet specifications for product life, shelf life, and battery performance, among others.
- 69. Devicix additionally breached its warranties by designing and developing a product that contained a variety of latent defects as set forth above.
 - 70. OrthoAccel provided Devicix timely notice of its breach.

- 71. Following the breach and notice, Devicix refused to remedy any of the identified defects unless OrthoAccel agreed to pay Devicix to correct the defects. Even after being paid for such remedial work, Devicix was unable to remedy its breaches.
- 72. The Contract purports to limit Devicix's liability and limit OrthoAccel's remedies for breach of warranties, however the circumstances of this dispute cause Devicix's attempted damage limitations to fail of their essential purpose and are unconscionable.
- 73. Devicix's breach caused damages to OrthoAccel in an amount in excess of \$75,000.

SIXTH CLAIM FOR RELIEF Fraud

- 74. OrthoAccel incorporates herein all paragraphs previously set forth.
- 75. As detailed above, Devicix made representations to OrthoAccel about Devicix's ability to remedy the problems in the design and development of the AcceleDent Aura product. Specifically, after numerous problems with the design process, in September 2012 Devicix assured OrthoAccel that it had the ability to, and would, resolve the problems with the device and design process.
 - 76. Devicix's representations were false.
 - 77. The representations concerned past or present facts and were material.
 - 78. The representations related to information that is susceptible of knowledge.
- 79. Upon information and belief, Devicix knew the representations to be false and, to the extent that the representations included promises about future conduct, Devicix lacked the present intent to fulfill its promises.

- 80. Devicix made these representations with the intent to induce OrthoAccel to act. Specifically, Devicix intended to induce OrthoAccel not to terminate the Contract and to continue to issue work orders and payments to Devicix for its services.
- 81. OrthoAccel was induced to act by these representations. Specifically, OrthoAccel did not terminate the Contract, continued to issue work orders and payments for Devicix's services, and launched the AcceleDent Aura product to market.
- 82. OrthoAccel acted in reliance on the representations made by Devicix. OrthoAccel's reliance was justified because the representations specifically related to Devicix's experience and capabilities, which were uniquely within Devicix's knowledge.
- 83. Devicix's misrepresentations caused damages to OrthoAccel in an amount in excess of \$75,000.

SEVENTH CLAIM FOR RELIEF Unjust Enrichment

- 84. OrthoAccel incorporates herein all paragraphs previously set forth.
- 85. OrthoAccel paid Devicix for providing design and development services, based on Devicix's representations that Devicix was qualified to, would, and did, design and develop a functional product.
- 86. Once defects in the design of the AcceleDent Aura device were discovered, Devicix promised OrthoAccel that it was able to and would correct these defects.
- 87. Devicix demanded additional payments to correct the problems discovered in its initial designs.
- 88. Despite receiving multiple payments for its design and development work, Devicix's resulting product design still contained extensive latent defects.

89. Devicix received financial benefit from the financial transaction despite the fact

that it failed to provide the services for which it was paid.

90. It would be unjust to allow Devicix to retain the proceeds it received for services

that it fraudulently solicited OrthoAccel to pay for at the outset and those proceeds it received

after demanding additional payments to correct the problems in its initial designs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant including economic and

non-economic damages to Plaintiff in an amount in excess of \$75,000 as provided by law and to

be supported by the evidence at trial and such other and further relief as this Court deems

appropriate.

JURY DEMAND

Plaintiff requests a trial by jury on all issues so triable.

Respectfully submitted this 13th day of March, 2015.

NORTON ROSE FULBRIGHT US LLP

By: s/ Matthew D. Spohn_

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Attorneys for OrthoAccel Technologies, Inc.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA

OrthoAccel Technologies Inc.,)
Plaintiff,) Civil Action No
V.)
Devicix, LLC,) AFFIDAVIT OF EXPERT REVIEW
Defendant.)
Matthew Spohn, being of lawful age a	nd being first duly sworn upon her oath, states

Matthew Spohn, being of lawful age and being first duly sworn upon her oath, states as follows:

- 1. I am Senior Counsel with the law firm Norton Rose Fulbright US LLP, and am engaged in the representation of Plaintiff OrthoAccel Technologies Inc. ("OrthoAccel") in the above-captioned action.
- 2. I have reviewed the facts of the above-captioned action with an expert whose qualifications provide a reasonable expectation that the expert's opinions could be admissible at trial and, in the opinion of this expert, the Defendant Devicix, LLC deviated from the applicable standard of care and by that action caused injury to OrthoAccel.

Dated March <u>13</u>, 2015

Matthew D. Spohn, #39639

The foregoing instrument was subscribed and sworn to before me by Matthew Spohn on this 1/3 day of March, 2015.

Witness my hand and official seal.

GEGILA, KENNEDY
NOTARY PUBLIC
STATE OF COLORADO
MY COMMISSION EXPIRES 7/29/2015

Notary Public

My Commission Expires: